SOUTH AFRICA

Law and Practice

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Spoor & Fisher

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Spoor & Fisher is a leading intellectual property firm that specialises in intellectual property (IP) law. The firm was established in 1920 and has since grown to become one of the largest and most respected IP firms in Africa. It provides a comprehensive range of legal services related to patents, trade marks, copyright, IP litigation, commercial IP transactions and IP portfolio management. The firm has a team of experienced attorneys, patent agents and technical specialists who serve clients in various industries, including pharmaceuticals, biotechnology, telecommunications and consumer goods. Spoor & Fisher has a strong reputation for excellence in the IP field and is consistently ranked among the top IP firms in South Africa and Africa as a whole. The firm has also been recognised internationally for its work in IP, receiving numerous awards and accolades over the years.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Regulation of the South African Pharmaceutical sector is primarily governed by The Medicines and Related Substances Act 101 of 1965 ("Medicines Act"), and the published Regulations thereto. These include the General Regulations to the Medicines and Related Substances Act, published under Government Notice 859 in Government Gazette 41064 of 25 August 2017 ("General Regulations"), which deal with general issues such as the registration and supply of medicines and requirements for permits and authorisations, including for conducting clinical trials. Regulations dealing with specific issues include, for example: (i) Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, published under Government Notice R1102 in Government Gazette 28214 of 11 November 2005 ("Transparent Pricing Regulations"); (ii) Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices (IVDs), published under Government Notice 1515 in Government Gazette 40480 of 9 December 2016 ("Medical Devices Regulations"); and (iii) Regulations Relating to the Period and Manner of Appeal Against Decisions of the Medicines Control Council, published under Government Notice R906 in Government Gazette 14826 of 28 May 1993 ("Appeal Regulations").

In addition, the Minister of Health is enabled to publish Notices in the Government Gazette relating to administrative aspects in terms of the Medicines Act and several such Notices have been published.

The regulatory body charged with administering the Medicines Act is the South African Health Products Regulatory Authority (SAHPRA), which took over administration of the Medicines Act from its predecessor, the Medicines Control Council (MCC). Both the MCC and the SAHPRA have issued several guidelines relating to various aspects of registration of medicines.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Administrative and Judicial Review

Under generally applicable administrative review provisions, an administrative action (a decision or omission in making a decision by a person exercising a public power or function) is subject to review under certain circumstances. The grounds for review include:

- the administrator was not authorised;
- a compulsory and material requirement was not complied with;
- the action was procedurally unfair;
- the action was materially influenced by an error in law;
- the action was taken for an ulterior purpose; or
- the action was unlawful or unconstitutional.

Challenging Pharmaceutical and Medical Device Regulators

A decision by the Director-General under the Medicines Act may be challenged by an aggrieved person by making written representations to the Minister within 30 days.

Any decision by the SAHPRA may be appealed on notice to the CEO of the SAHPRA within 30 days. The CEO must attempt to resolve the matter, failing which an appeal committee will be

formed. Any decision by the appeal committee is subject to judicial review.

1.3 Different Categories of Pharmaceuticals and Medical Devices

The Medicines Act provides for the regulation of health products intended for human and animal use including medicines, medical devices and IVDs, radiation-emitting devices and radioactive nuclides, complementary medicines and veterinary medicines. In terms of the General Regulations, medicines, including veterinary and complementary medicines, are classified as Category A, B, C or D medicines. Medical devices are similarly classified as Class A, B, C or D devices based on an assessment of the manufacturer's or distributor's intended use, the level of risk to users, the degree of invasiveness, and the duration of use and exposure. Although differing levels of supporting data will be required, each of the above-mentioned categories is regulated, in terms of the Medicines Act, by the SAHPRA. The SAHPRA has issued guideline documents for each category that detail the approach to be followed and the information required in the registration process. The Medicines Act and regulations do not make special provision for biologics, but separate guideline documents have been issued by the SAHPRA.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Non-clinical studies and clinical trials are provided for under the provisions relating to access to unregistered medicines in the Medicines Act. In terms of these provisions, the SAHPRA may authorise the sale of an unregistered medicine to a specific person or institution for the purpose of conducting clinical trials. The General Regulations to the Medicines Act set out the specific requirements for conducting clinical trials and investigations for medicines. In terms of these requirements, anyone wishing to initiate or conduct clinical trials must apply to the SAHPRA for authorisation to conduct such a trial by submitting the required fee, together with the stipulated information.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

In terms of the requirements set out in the Medicines Act and the General Regulations, anyone wishing to initiate or conduct clinical trials must apply to the SAHPRA for authorisation to conduct such a trial by submitting the required fee and stipulated information. There are set dates approximately every six weeks for submission of clinical trial applications to the SAHPRA, with the deadline published on its website. Once the clinical trial application is received it is screened and allocated to an evaluator within two weeks of the submission date and either rejected for being deficient or accepted for review, whereupon the evaluator reviews the study and submits its report to the clinical trials committee. Approximately six to eight weeks after the submission date, the clinical trials committee meets to discuss the report and provide its recommendation. Thereafter, the recommendation is communicated to the applicant, within ten weeks of the submission due date. In cases where the investigational product is unfamiliar, the submission may be referred to external reviewers or other committees of the SAHPRA for input, and the turnaround time may be prolonged.

2.3 Public Availability of the Conduct of a Clinical Trial

It is a requirement that all new clinical trials conducted in South Africa be registered in the South African National Clinical Trials Register (SANCTR), an official registry and member of

the World Health Organisation (WHO) Network of Primary Registers. The SANCTR provides a publicly searchable database including updated information on clinical trials on human participants conducted in South Africa. This information includes the purpose of the trial, details of who can participate, where the trial is located, and contact details.

The database ensures that the WHO-stipulated minimum dataset for registered trials is publicly and freely available to all users of the registry. It includes information on the questions being investigated, findings of studies, locations, funders, funding and research institutions involved. Further, principal investigators are obliged to ensure the reporting of the trial and its findings.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions on using online tools to support clinical trials, including for recruiting or monitoring purposes, provided that the data integrity and accuracy is maintained at all times.

2.5 Use of Data Resulting From Clinical Trials

The Protection of Personal Information Act, No 4 of 2013 (POPIA) commenced on 1 July 2020, with a one-year grace period to comply. POPIA was enacted to promote the protection of personal information processed by public and private bodies and to establish minimum requirements for the processing of personal information. The Academy of Science of South Africa has published a draft POPIA Code of Conduct for Research (POPIA Research Code) for public comment. However, POPIA and the POPIA Research Code only apply to identifiable personal information, and data is not considered personal data if it has been permanently de-identified or anonymised. Thus, clinical trial data is not considered personal, provided it is permanently anonymised and can be transferred.

2.6 Databases Containing Personal or Sensitive Data

Any database containing personal or sensitive data, that is data that is not permanently anonymised, would be subject to the requirements of POPIA. In terms of POPIA, such data may only be processed in a fair and lawful manner and only with the consent of the data subject. Such data may only be processed for specific, explicitly defined and legitimate reasons and may not be processed for a secondary purpose unless that processing is compatible with the original purpose and with the consent of the subject.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The assessment process and the related criteria for determining whether or not a product should be classified as a pharmaceutical or as a medical device should start with the definitions of "medicine", "medical device", and "IVD", provided in the Act. Where a reagent is used in vitro, alone or in combination, the product will be classified as a device. The regulations also deal with a "combination device" which is a device that incorporates a substance, which if used separately, would be considered a medicine. An application for registration of a medical device must provide the particulars of the scheduled substance or biological substances contained therein, which substances will require a separate registration as a medicine. Application may also be made to

transfer information pertaining to a medicine to the register for medical devices or IVDs.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

For biologic medicinal products, there are specific obligations that must be fulfilled in South Africa for granting a marketing authorisation. The SAHPRA has set out specific guidelines and requirements to ensure that biologic medicinal products are safe, effective and of high quality. These obligations include:

- conducting clinical trials;
- providing scientific data to demonstrate safety and efficacy;
- providing information on the manufacturing process and quality control measures;
- conducting post-market surveillance;
- complying with labelling and packaging requirements;
- providing updates to the SAHPRA regarding any changes to the manufacturing process; and
- complying with all relevant regulations and guidelines.

It is worth noting that the authorisation process for biologic medicinal products may be more complex and time-consuming than for other medicinal products due to the nature of these products and the need for extensive data on their safety and efficacy.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The period of validity of marketing authorisation for pharmaceuticals and medical devices varies depending on the product and its characteristics. The initial period of validity for a marketing authorisation is ordinarily five years, but this period can be shorter or longer depending on the specific product and its intended use.

Marketing authorisation can be renewed for a further period of five years if the product continues to meet the necessary requirements for safety, efficacy and quality.

The SAHPRA can revoke a marketing authorisation:

- if the product is found to be unsafe, ineffective or of poor quality;
- if the holder of the authorisation fails to comply with the conditions of the authorisation; or
- if it fails to place the product on the market within a certain time frame.

The SAHPRA can also vary, suspend or withdraw a marketing authorisation under certain circumstances, such as if new safety concerns arise or if the product is found to be in violation of any regulatory requirements. The procedures for varying, suspending or withdrawing a marketing authorisation are outlined in the Medicines and Related Substances Act (Act 101 of 1965) and its associated guidelines.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

The procedure for obtaining a marketing authorisation for pharmaceuticals and medical devices in South Africa involves submitting an application to the SAHPRA.

The application must include:

- particulars of the applicant and the prospective holder of the certificate of registration;
- data on the safety, efficacy and quality of the product;

- a copy of the manufacturing licence;
- a copy of the current GMP certificate from the regulatory authority in the country where the product is manufactured; and
- details of the labelling and packaging.

The application is evaluated by the SAHPRA, and if all requirements are met, the marketing authorisation is granted.

The procedure for variation of a marketing authorisation involves submitting a variation application to the SAHPRA. The variation application should include all relevant data and information related to the proposed changes, such as changes in the therapeutic indication, formulation, posology, patient population, packaging and/or labelling. The SAHPRA will evaluate the variation application and determine if the changes are acceptable and whether the marketing authorisation can be amended.

It is permissible to transfer a marketing authorisation from one marketing authorisation holder to another. The transfer process involves submitting a variation application to the SAHPRA. The new marketing authorisation holder must meet all the requirements and obligations set out in the original marketing authorisation.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

In terms of Section 21 of the Medicines Act, the SAHPRA may authorise anyone to sell a specified quantity of an unregistered medicine, medical device or in vitro diagnostic to a specified person or institution for a specified period. Such approval may be withdrawn at any time by the SAHPRA. This section governs both clinical trials, as well as named-patient or compassionate use programmes.

Such application must be made online by a treating medical practitioner, who must provide details of the pharmaceutical or medical device, evidence of compliance with good manufacturing standards and reasons why a registered medicine cannot be used, together with the prescribed fee. Authorisation granted under Section 21 typically lasts for six months, following which re-authorisation must be requested.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

The holder of a marketing authorisation for a pharmaceutical or medical device is required to comply with ongoing obligations, including pharmacovigilance and technovigilance activities. These obligations entail monitoring, detection, assessment, understanding and prevention of adverse effects or incidents associated with the use of the product.

The holder of the marketing authorisation is required to report any suspected adverse reactions or incidents to the SAHPRA as per the prescribed requirements. The SAHPRA may also impose post-marketing obligations, including Phase IV trials, as part of the marketing authorisation, based on the evaluation of the risk-benefit profile of the product.

The holder must comply with these obligations and submit the required data to the SAHPRA within the specified timelines. Failure to comply with these obligations may result in sanctions, including revocation of the marketing authorisation.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Third parties can access limited information regarding pending applications for marketing authorisation for pharmaceuticals and medical devices through the SAHPRA website. The information available includes the name of the product, the applicant's name, and the date the application was received. However, detailed information, such as clinical trial data or proprietary information, is not publicly available during the application process.

Once a marketing authorisation has been granted or refused, the decision and the reasons for it are made public on the SAHPRA website. Third parties can also request access to non-confidential portions of the marketing authorisation application through a formal request to the SAHPRA.

Commercially confidential information and personal information are protected under South African law. The SAHPRA may redact or withhold information that is considered commercially confidential or sensitive personal information, such as patient data or trade secrets, from the publicly available information. However, the SAHPRA is required to balance the public interest in accessing information against the protection of commercial or personal information.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The Medicines Act and National Health Act provide for measures against contraventions in respect of medicines and medical devices. Inspectors under the Medicines Act may enter a premises relating to medicines or medical devices at reasonable times, and may inspect or seize such medicines or devices as evidence of contravention, or take samples necessary for further testing. Officials under the National Health Act may similarly enter health establishments to ensure compliance and obtain evidence of non-compliance, including search and seizure with a warrant. Various sanctions for contravention are available under the two Acts, including:

- fines;
- imprisonment;
- written warnings;
- revocation of compliance certificates; or
- referral to the National Prosecuting Authority.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

Counterfeit goods, especially in relation to pharmaceutical and medical devices, represent a dire societal epidemic considering that their utility, as substandard goods, bears a strong possibility of adversely impacting the health and quality of healthcare treatment received by the general population. In terms of the counterfeit pharmaceuticals, most of these contain inter alia no active/substandard/illegal ingredients or incorrect dosages and their ingestion – especially where necessary for the management of life-threatening diseases – can prove fatal to the end-user. In relation to medical devices, the same concerns apply: the lower quality of equipment that is used when handling someone's life is of great concern because medical devices, in their ordinary sense, will not work as intended or cost someone their life due to inadequate use/functionality. Whilst they have gained popularity for their low cost amongst the less affluent groups, it nonetheless poses a danger to enable these goods to enter the South African channels of commerce.

One of the main purposes of the Counterfeit Goods Act is to prevent the release of counterfeit goods into the channels of commerce in South Africa. The Department of Customs and Excise ("Customs") is primarily responsible for monitoring the country's borders, including its ports of entry. To enable Customs to detain and seize any suspected counterfeit goods that are imported into South Africa, it is necessary for the owner of trade marks and/or copyright to file an application with the Commissioner for the South African Revenue Service (the "Commissioner") requesting such detention and seizure. This is governed by Section 15 of the Counterfeit Goods Act and the application filed is commonly referred to as "the Section 15 application".

In order to improve the success rate of counterfeit goods identification, sufficient training is required on how to identify them. Training of customs officials to maintain up-to-date knowledge of how counterfeiters are counterfeiting medical devices and pharmaceuticals is crucial. To promote this, brand awareness seminars and training sessions are necessary and, in conjunction with the experts from the brand owners, Customs officials can understand the intricacies of the goods and differentiate between that which is genuine and that which is not. Through this, Customs officials are given a basis of knowledge in what to immediately hone in on and look for when examining cargo.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Manufacturing plants of pharmaceutical products and medical devices require a licence in terms of Section 22(C)(1)(b) of the Act. The application for registration as a manufacturer is made to the SAHPRA on the relevant Form, supported by the documentary proof specified in the General Regulations. A licensed manufacturer may validly conduct all operations including purchasing, processing, production, packaging, releasing, and storage and shipment. An annual renewal fee is payable and the licence is valid for a period of five years from the date of issue. In addition to the SAHPRA manufacturer's licence, an application will also require a site licence from the Department of Health and registration as a manufacturing pharmacy with the South African Pharmacy Council.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Establishments engaged in wholesale of pharmaceutical and medical devices also require a licence in terms of Section 22(C)(1)(b) of the Medicines Act. As with the manufacturer's licence, application for registration as a wholesaler is made to the SAHPRA on the relevant form, supported by the documentary proof specified in the General Regulations. In terms of the Regulations, a "wholesaler" is a person or entity that holds, stores, delivers or purchases medicines or scheduled substances from a

manufacturer and sells into the retail sector or to any person that may lawfully possess such substances. The licence is valid for a period of five years provided annual renewal fees are paid.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceutical products are scheduled as one of Schedule 0–8 for the purposes of sale, possession or manufacture. A consolidated list of the scheduled substances is available from the SAHPRA.

Schedule 0 substances may be sold in an open shop. Schedule 1 substances may only be sold without a prescription by a certain list of qualified individuals, and may not be sold to persons under the age of 12 years except where certain requirements are met. Schedule 2 substances may be sold without a prescription. The sale of Schedule 2, 3, or 4 substances may be repeated if indicated on the prescription, but not for longer than six months. Schedule 5 substances may only be prescribed for longer than six months if certain conditions are met. The sale of Schedule 6 substances may only be repeated on a new prescription and may only be sold for a course of not more than 30 days. Schedule 5 and 6 substances may be sold for use for a period of 48 hours in emergency situations on a verbal instruction, provided a written prescription is issued with 72 hours.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The importation and exportation of pharmaceuticals and medical devices in South Africa are governed by various laws and regulations, including the Medicines and Related Substances Act, the Customs and Excise Act, and the International Trade Administration Act.

The SAHPRA is the authority responsible for regulating the importation of pharmaceuticals and medical devices into South Africa. The SAHPRA applies import regulations at the point of entry to ensure that imported products comply with South African regulatory requirements.

Other entities that are involved in enforcing import regulations in South Africa include the South African Revenue Service (SARS), which is responsible for collecting customs duties, and the Department of Health, which has the power to prohibit the importation of certain pharmaceuticals and medical devices that do not meet South African regulatory requirements.

In addition to these entities, the National Regulator for Compulsory Specifications (NRCS) is responsible for enforcing technical regulations relating to the safety, health and environmental protection of products imported into South Africa, including medical devices. The NRCS ensures that imported products comply with relevant South African technical regulations and standards.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Any person who is a resident of South Africa, or who has a physical presence in the country, may act as the importer of record for pharmaceuticals and medical devices.

There are, however, specific requirements that must be met by the importer of record. The importer must be registered with the South African Revenue Service (SARS) as an importer and must hold a valid import licence issued by the Department of Health. The importer must also comply with all applicable regulations, including those related to labelling, packaging and storage of the products.

In addition, the importer must be able to demonstrate that the products being imported comply with all applicable regulations, including those related to safety, efficacy and quality.

It is important to note that the importer of record is responsible for ensuring that the products being imported comply with all applicable regulations and for any costs or liabilities associated with non-compliance.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Importation of pharmaceuticals and medical devices into South Africa is subject to prior authorisation, and the importer must hold a valid import permit issued by the SAHPRA. Without this permit, the importation of pharmaceuticals and medical devices is prohibited.

There are however certain exemptions available in terms of the Medicines and Related Substances Act (Act 101 of 1965) and the Medical Device Regulations of 2017, which provide relief from the requirement for prior authorisation for the importation of pharmaceuticals and medical devices.

Some of these exemptions include:

- personal use exemptions;
- emergency use exemptions;
- special use exemptions;
- low-risk medical device exemptions; and
- in vitro diagnostic medical device exemptions.

It is important to note that each exemption has its own specific criteria, and the importer must comply with all applicable requirements to qualify for the exemption.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

In South Africa, non-tariff regulations and restrictions (NTRs) on the importation of pharmaceuticals and medical devices are imposed by the Department of Health (DOH) and the SAHPRA under the authority of the Medicines and Related Substances Act, 1965 (Act No 101 of 1965). The NTRs are mainly based on the regulatory category of the products and are aimed at ensuring that imported pharmaceuticals and medical devices comply with the applicable standards, specifications and regulations.

Import permits and licences are generally required for the importation of pharmaceuticals and medical devices, depending on their regulatory category. The specific types of products subject to NTRs upon importation are listed in the Schedules to the Medicines and Related Substances Act, 1965, which include the Schedules of Medicines, Scheduled Substances, and Scheduled Devices. The Schedules categorise products according to their regulatory require-

ments, including registration, notification or exemption, and the importation requirements for each category are set out in the relevant regulations.

6.5 Trade Blocs and Free Trade Agreements

South Africa is a member of several trade bloc or free trade agreements that include provisions relating to the trade in pharmaceuticals and medical devices, and/or touch on regulatory standards or include statements in support of harmonisation. Examples include the Treaty of the South African Development Community (SADC Treaty), Agreement Establishing the African Continental Free Trade Area (AfCFTA), and the SADC-EU EPA (Economic Partnership Agreement (EPA) between the SADC EPA States, of the one Part and the European Union and its Member States, of the other Part). In addition, the SAHPRA provides for, and encourages, the use of reliance-based evaluations of products registered with a recognised regulatory authority (RRA). The RRAs include the European Medicines Agency Centralised Procedure (EMA CP); European Medicines Agency Decentralised Procedure (EMA DCP); Health Canada; the EU's Mutual Recognition Procedure (MRP); EU National Procedures; Medicines and Health Products Regulatory Agency; UK (MHRA); Ministry of Health, Labour and Welfare (MHLW), Japan; Swiss Agency for Therapeutic Products (Swissmedic); Therapeutic Goods Administration, Australia (TGA); the Unites States Food and Drug Administration (US FDA); and WHO listed Authorities (WLA).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The Medicines Act provides for a transparent pricing system and establishes a Pricing Committee tasked with overseeing the pricing of medicines and scheduled substances. The relevant regulations that govern pricing of medicines are the Regulations Relating To A Transparent Pricing System For Medicines And Scheduled Substances published under Government Notice R1102 in Government Gazette 28214 of 11 November 2005 (Pricing Regulations), as amended.

The Pricing Regulations establish a single exit price for each pharmaceutical. In terms of the Medicines Act and Pricing Regulations, no pharmacist, wholesaler, distributor or anyone permitted to sell medication may sell a medicine to anyone other than the State at a price higher than the single exit price. The Pricing Regulations provide for the charging of a dispensing fee by pharmacies; however, this is also strictly regulated.

The single exit price is made up of:

- the price determined by the manufacturer or importer;
- a logistics fee; and
- VAT.

In terms of the Pricing Regulations, the manufacturer or wholesaler must publish a schedule specifying the single exit price of a medicine or scheduled substance, as well as the logistics fee. The logistics fee is determined by agreement between a logistic services provider and the manufacturer or importer, which must be less

than the maximum logistics fee set by the Pricing Committee.

The single exit price may only be increased by the Minister of Health, on the recommendation of the Pricing Committee and taking into account several factors mentioned in the Pricing Regulations, including international pricing information, changes in foreign exchange rates and the need to ensure the availability, affordability and quality of medicines.

7.2 Price Levels of Pharmaceuticals or Medical Devices

The single exit price is determined by the Pricing Committee according to a methodology that conforms with international benchmarks, taking into account the price, and factors that influence price, at which the medicine or an equivalent thereof is sold in other countries in which the prices of medicines are regulated and published.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The WHO advocates that procurement of medicines should take place against a list of essential medicines. In South Africa, there is a distinction between the procurement and pricing reimbursement of pharmaceuticals in the public sector versus the private sector.

In the public healthcare sector, the national selection of medicines available for procurement is provided for by the National Essential Medicines List Committee (NEMLC) and on a local level by the provincial and facility-based Pharmacy and Therapeutics Committees (PTCs). The State, through the National Department of Health, prepares, advertises, adjudicates, awards and manages the national medicines tenders. In terms of the tender process, pricing is evaluated critically on the basis of global trends in active pharmaceutical ingredient (API) price increases and formulation costs.

In the private healthcare sector, there is no reimbursement from public funds and clinical decisions regarding the selection of medicines are made within each medical scheme, as implemented by medical scheme administrators. The selection of medicines for private sector schemes is dependent on the type or class of medicine. For high-volume, low-cost medicines the selection is generally based on price. Where high-cost medicines are considered for selection, these are subject to a more thorough evaluation, which includes clinical efficacy and effectiveness, cost-effectiveness and budget impact on the medical scheme.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

In the private health sector, each medical scheme is allowed to use a selection process to create its own prescribed minimum benefit formulary on the basis of principles of evidence-based medicine, cost-effectiveness and affordability.

In the public health sector, the selection and pricing of medicines is subject to a tender process, the review of which includes a pharmacoeconomic analysis. However, this analysis merely informs whether a particular pharmaceutical will be procured and not necessarily the price at which it will be reimbursed.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

The Pricing Regulations specify the dispensing fee that may be charged with respect to the sale of any medicine. The maximum dispensing fee is calculated as a base amount plus a percentage of the single exit price of the medicine. Four cat-

egories are provided for, where the percentage of the single exit price for dispensing low-cost medicines is higher and the percentage of the single exit price for dispensing higher cost medicines is lower. The dispensing fee is reviewed annually by the Minister of Health.

8. Digital Healthcare

8.1 Rules for Medical Apps

Medical apps may be considered medical devices depending on their intended use and how they work. Medical apps that provide medical services for humans or animals relating to diagnosis, prevention, monitoring or treatment of diseases or injuries, or even relating to control of conception, fall within the legislative definition of a medical device in the Medicines Act. Accordingly, such medical apps are subject to the same rules and prescripts for medical devices.

8.2 Rules for Telemedicine

Regulation of Physicians and Telemedicine

Telemedicine is governed by the Health Professions Council of South Africa (HPCSA), as well as by legislation, including the Health Professions Act and National Health Act. Physicians may provide medical attention through mobile devices. Any telemedicine providers, including cross-border providers, must be registered in terms of the Health Professions Act and are subject to the ethical rules of conduct of the HPCSA. Cross-border telemedicine providers serving South African patients must be registered with the regulatory bodies in their respective countries, in addition to with the HPCSA.

Telemedicine Guidelines

The HPCSA guidelines provide that "Telehealth should preferably be practised in circumstances where there is an already-established practitioner-patient relationship. Where such a relationship does not exist, practitioners may still consult using Telehealth provided that such consultations are done in the best clinical interest of patients".

8.3 Promoting and/or Advertising on an Online Platform

Promotion or advertisement of medicines or medical devices on online media, including web pages or social media, is governed by the same regulations for any other form of promoting or advertising of such health products. Further, electronic promotion is not permitted unless, on first contact with a person, an option to opt out of further electronic communication is provided clearly and the decision in respect thereof is subsequently respected by the promoter. A comprehensive set of rules is applicable to advertising of medicines and medical devices, and is not set out here in detail. However, some of the provisions include that:

- scheduled medicines may only be advertised if registered;
- advertisements must be complete, clear and accurate, and not misleading in any form;
- advertisements may not disparage competitor products; and
- advertisements may not be set out in a manner relating to trade marks or otherwise that leads to the deception or confusion of consumers or practitioners as to the origin of the products.

8.4 Electronic Prescriptions

Electronic prescriptions are allowed in South Africa. A prescription prepared electronically must be in compliance with the Electronic Communications and Transactions Act, and if signed electronically, must be signed with an advanced electronic signature. The HPCSA guidelines pro-

vide that prescriptions must be issued under a practitioner's personal and original signature, which includes electronic signatures that meet the prescribed requirements. For Schedule 1 to 4 medicines the prescriptions may be computer generated, but for Schedule 5 to 8 medicines the prescriptions may be handwritten only and accordingly cannot be issued electronically.

The guidelines of the Digital Healthcare Association require that electronic scripts must be sent directly a patient's pharmacy of choice, and not to the patient to forward to the pharmacy.

Lastly, it is not an acceptable standard of care for prescriptions issued via telemedical services to be based solely on an online questionnaire.

8.5 Online Sales of Medicines and Medical Devices

The online sales of medicines and medical devices is generally governed by the same regulations for other forms of sale. There are no provisions prohibiting the online sale of medicines and medical devices, and accordingly such sale is permitted.

8.6 Electronic Health Records

Electronic Records and Health-Related Information

Electronic records are regulated generally by the Electronic Communications and Transactions Act (ECTA), and therefore include electronic health records. The National Health Act provides specifically that controls measures must be set up to prevent unauthorised access to health records.

Health-related information specifically is included in the definition of "personal information", which is governed in terms of the POPIA, in terms of which strict provisions are made for the lawful processing of personal information. Health-related information may strictly not be processed except by healthcare professionals or institutions, including insurance companies and medical schemes, as well as various other bodies under specific circumstances. The POPIA provides for the strict integrity, security and confidentiality of personal information.

The HPCSA guidelines also provide that arrangements must be made for proper security of electronic health records, including storage and transmission thereof, using internationally accepted standards. Passwords must be required for the access of health records in electronic format.

Cloud Platforms

There are not provisions in healthcare legislation specific to cloud platforms. Notwithstanding this, subject to the provisions of the ECTA and POPIA, and other measures put in place such as those of the HPCSA, regarding personal information, confidentiality and security, it would be permissible to transfer and store health-related data of patients on cloud platforms. Should a cloud platform be hosted outside of South Africa, the transfer of health-related information to a foreign country must be authorised, either by legislation or by the relevant regulatory body.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The South African Patents Act governs patents in South Africa. Under the Act, a patent provides the patent holder with the exclusive right to prevent others from making, using, exercising, dis-

posing of, or offering to dispose of the invention within South Africa, without their consent.

In practice, one common issue faced by pharmaceutical and medical device products under the Act is the question of whether a particular invention is patentable subject matter. Section 25(2) of the Act sets out certain exclusions from patentability, such as methods of treatment of the human or animal body by surgery or therapy, and diagnostic methods.

Another issue that may arise is the question of whether an invention is new and inventive. To be patentable, an invention must be new and inventive, which means it must not have been previously disclosed or made available to the public and must not be obvious to a person skilled in the art.

In addition to the general requirements for patentability, pharmaceuticals and medical devices may also be subject to specific patentability requirements. For example, Section 27(1) of the Act requires that an invention in the pharmaceutical field must involve a new chemical entity or a new use of a known chemical compound, and that the invention must be capable of being used in trade or industry.

9.2 Second and Subsequent Medical Uses

In South Africa, second and subsequent medical uses of a known product may be regarded as patentable subject matter. The South African Patents Act does not explicitly exclude second and subsequent medical uses from patentability. Therefore, claims directed to such uses may be patentable, provided that the relevant patentability criteria are met, including novelty, inventive step and industrial applicability. Additionally, in terms of decided South African case law, a claim directed to a first medical use should be drafted in the "for use type" claim format and a claim directed to a second medical use should be drafted in the "Swiss-type" claim format.

In relation to new dosage regimes and new or selected patient populations, such inventions may also be patentable subject matter, on condition that they meet the relevant patentability criteria.

Infringement of a second and subsequent patent of a pharmaceutical product may occur where an infringing party exploits the patented invention without the permission of the patent owner. This may include activities such as manufacturing, importing, offering for sale, selling or using the patented invention. The scope of the patent and the alleged infringing activity will be assessed by the courts in order to determine whether infringement has occurred.

9.3 Patent Term Extension for Pharmaceuticals

South African law does not make provision for, or include any mechanism whereby the term of a patent can be extended in any way. In fact, Section 69A of the Patents Act (a so-called Bolar provision) provides that certain non-commercial scale acts which are reasonably related to the obtaining, development and submission of regulatory information required under law will not be considered patent infringement. The proviso to this section is that no product may be stockpiled in anticipation of the first sale upon patent expiry.

9.4 Pharmaceutical or Medical Device Patent Infringement

A pharmaceutical or medical device patent may be infringed by unauthorised:

- making;
- use;
- exercise;
- disposition (eg, sale);
- offering to dispose (eg, advertisement); or
- importation.

Applying for marketing authorisation in itself does not constitute patent infringement. It may in certain instances, along with other factors, contribute to an apprehension that the applicant may launch an infringing product once marketing authorisation has been obtained, which may form one of the grounds for applying for an interim interdict (injunction), pending the outcome of a final action. Such an application, by its very nature, requires urgency, and amongst other things, it must be shown that there is a well-grounded apprehension of irreparable harm if the interim relief is not granted and ultimate relief is eventually granted.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Defences to Patent Infringement

Specific defences to patent infringement in relation to pharmaceuticals and medical devices include Bolar-type defences. Acts conducted for the purpose of acquiring regulatory approval do not constitute patent infringement. However, the acts must be conducted in good faith, on a non-commercial scale and solely for the purposes reasonably related to obtaining regulatory approval.

Compulsory Licences

Compulsory licences of patents, including those relating to pharmaceutical products and medical devices, are provided for in South African patent law. Application may be made for a compulsory licence on two grounds:

- where the working of a patent without the infringement of a prior patent is dependent on obtaining a licence under the prior patent; and
- where patent rights are abused.

Patent rights are considered abused if:

- the patented invention is not worked to an adequate extent after a certain period subsequent to the application or grant of the patent, without satisfactory reason;
- the demand for the patented article is not adequately met;
- the trade or industry or agriculture is prejudiced by the refusal of the patentee to grant a licence reasonably or at all, and it is in the public interest that a licence be granted; or
- the demand for the patented article is met by importation, but at excessive prices.

9.6 Proceedings for Patent Infringement

Who May Institute Proceedings?

Patent infringement proceedings may be brought by the patentee, or in certain instances by a licensee under a licence of right, where the patentee refuses to institute proceedings after being called upon by the licensee to do so.

Relief

A successful plaintiff may obtain an interdict, delivery up, damages or a reasonable royalty instead of damages, and may recover legal costs.

Procedure

Patent infringement proceedings are typically instituted by way of action, commenced by issuing a combined summons, together with a particulars of claim. The defendant has an opportunity to defend the action, and will be required to deliver a plea to the particulars of claim, and

a counterclaim, if any. The plaintiff is afforded an opportunity to replicate to the defendant's plea, and plea to the counterclaim, following which the defendant may replicate to the plea in reconvention. This is followed by discovery and expert summaries, and any other interlocutory proceedings, and thereafter a trial date may be allocated.

Invalidity is available as a defence in an infringement action, and is instituted by way of counterclaim.

9.7 Procedures Available to a Generic Entrant

South African patent law makes provision for a declaration as to non-infringement should an applicant wish the courts to adjudicate on the question of whether or not there is or will be patent infringement. "Clearing the way" is not a requirement for generic market entry (ie, for obtaining marketing authorisation). The authorisation procedure for pharmaceuticals and medical devices does not take account of patent protection; ie, no provision is made in South African law for patent linkage.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Counterfeiting refers to the intentional and illegal production, or mislabelling, of goods regarding their identity and origin in order to appear as genuine and deceive customers into buying them. The pharmaceutical industry is worth almost USD1 trillion in sales annually, but the World Health Organisation (WHO) estimates that counterfeit medicines constitute more than 50% of the global drug market; a sizeable portion is experienced in developing countries. The groups distributing counterfeit medicines thrive mostly in countries where there are weak anti-counterfeiting laws; the legal actions are ineffective; and the pharmaceutical regulatory agencies are not efficient through being underfunded or understaffed. A similar trend is demonstrated with medical devices whereby, in 2010, the WHO revealed that 8% of the medical devices in circulation were known to be fake, but this is likely be an underestimate and also likely to be a much larger figure now.

There are three main sources of counterfeits entering channels of commerce: (i) national production; (ii) imported products which enter via the country's ports and borders; and (iii) independent manufacturers who produce counterfeit products. The first source refers to the manufacturing of counterfeit products in the domestic market and can be a consequence of outsourcing manufacturing to non-reputable manufacturers; the second pertains to the importation of fake items through the country's ports and borders; and the third relates to independent manufacturers producing counterfeit goods.

The similarity between these two industries, especially within the realm of counterfeits, is that they enter the market through the supply chain. With medical devices, criminals can invade the ecosystem through sneaking counterfeit medical devices into local hubs and, due to the complexity of the healthcare supply chain and the equipment involved with that industry, it becomes attractive for counterfeiters to bring their products in at a fraction of the price. In respect of pharmaceuticals, a study conducted on the supply chain of counterfeit medicine also demonstrated that the distribution side of the business concerns non-reputable doctors and pharmacies who seek to purchase stock for a lower price than the genuine product, whereas

another case identified the counterfeit goods being imported.

A burgeoning concern is the proliferation of counterfeit medical devices and pharmaceuticals becoming available online. E-commerce has grown into a key channel for counterfeiters to reach larger audiences and the advertising of pharmaceuticals and medical devices – which are ordinarily expensive – are attractive to the less affluent, especially since e-commerce circumvents the geographical border and enables them to obtain these goods. Counterfeiters have adopted strategies where they can receive stock by a supplier only when they have an order and can thus act as a front selling directly to the consumer but not holding any of the counterfeit goods in their possession. Corroborating this issue is the ability to leave little or no record to trace back to the end-user and, with the lack of a regulatory environment/oversight mechanism on these transactions, the sale of these goods is likely to continue.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The Trade Marks Act 194 of 1993 (the "Trade Marks Act") was enacted to improve on the protection of trade marks and illuminate the intellectual property landscape in terms of what is permissible to be registered and the rights granted thereto. The Trade Marks Act permits a variety of different representations of a mark to be registered, and this is inclusive of shapes. However, Section 10 of the Trade Marks Act specifically provides for instances where the registration of a trade mark may be refused and, when it comes to registering a shape, pharmaceutical companies have encountered difficulties. One particular hurdle to overcome is the registrability of the shape of a medical pill because, regardless of the extensiveness and consistency of use, this is not a registrable trade mark. For a shape mark to be registered, it must overcome Section 10(5) of the Trade Marks Act, which stipulates that a mark which consists exclusively of the shape of the goods, where such a shape is necessary to obtain a specific result, may not be registered. In Beecham Group Plc v Triomed (Pty) Limited, it was held that the unique shape of a medical tablet, which was designed to make swallowing easier, is not registerable as a trade mark. Therefore, a pharmaceutical manufacturer cannot trademark the shape of the tablets that they use, nor the container utilised, thereby making them susceptible to counterfeits of their products being created.

Another hurdle to surmount is Section 10(11) of the Trade Marks Act which allows for a refusal to register a shape, container for goods, configuration, colour or pattern of goods where the registration of the mark will limit the development of an industry. The issue resides in the "colour depletion doctrine", which limits the number of colours available to an industry and forces the owners of the brand to operate within such parameters. This undoubtedly results in many of the same colour schemes for trade marks being utilised by the many entities in the industry and curtails, to a degree, the ability of the proprietor to act.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Trade Dress

In South Africa, instances of trade dress infringement are enforced by way of the "passing-off" course of action. This is a common law remedy which was defined in Capital Estates v Holiday Inns as a representation by a person that their business is that of another, or associate thereof, to the extent that members of the public may be

confused into believing that one business is that of another. To be successful with a passing-off claim, it must be proven that:

- there was a reputation existing in the mark;
- there is evidence of misrepresentation by the other mark to the extent that there exists a likelihood of confusion or deception; and
- that there was damage, assuming that misrepresentation was established.

The Supreme Court of Appeal case of Koni Multinational Brands (Pty) Ltd v Beiersdorf AG examined these factors in relation to two personal care items and concluded that, on the basis of inter alia shape, product type, colour and reputation, the products were deceptively confusing, and such parameters would likely also be canvassed when considering the trade dress of pharmaceuticals or medical devices. However, it is worth considering the dissenting judgment which, whilst only persuasive, had a valid point in finding from leading literature on the topic that the public will tend to focus primarily on the brand name of any other product, as supposed to the entire get up. This lends itself to the conclusion that a competitor utilising a different and distinguishable brand name from another is likely to avoid a finding of passing-off.

Designs

IP protection is also available for the design of pharmaceuticals (for example tablets), medical devices or their packaging, in the form of design registrations. In addition to being new and original, or new and not commonplace, the articles to which the design applies must also be intended to be multiplied by an industrial process.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

South African law does not provide for any form of data exclusivity for pharmaceuticals or medical devices. No provision is made for Orphan Drug or similar status. In fact, the South African regulatory landscape favours early market entry and includes provisions for the more affordable supply of medicines. In addition to Section 69A referred to above, the Act provides a system for the potential parallel importation, under certain circumstances, of medicines registered in South Africa but imported by a person other than the holder of the registration certificate, and that such importation will not be considered patent infringement.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

South Africa did not enact any special rules or regulations to aid the commercialisation or distribution of medicines and medical devices during the COVID-19 pandemic, nor were any rules relaxed. However, the SAHPRA did make use of the relevant provision in the Act which allows them to authorise the sale of unregistered medicines, medical devices and IVDs. The SAHPRA also partnered with other leading regulatory agencies during this time to ensure the availability of the medicines and devices required to respond to the pandemic. The SAHPRA made use of the provisions to allow for the supply of unregistered medicines to approve the use of several vaccines, ivermectin, and medical devices. Several of the vaccines initially approved under this process have now undergone full registration.

11.2 Special Measures Relating to Clinical Trials

The SAHPRA issued special guidelines relating to the inspection of clinical trial sites and other on-site inspections. In particular, in order to ensure safe on-site inspection of sites for compliance with Good Clinical Practice guidelines, the SAHPRA provided for remote virtual inspection of such sites, as well as the following of strict protocols for on-site inspection.

Furthermore, for ongoing trials, the SAHPRA issued a communication to all investigators requiring them to consider the circumstances of the trial and modify the study conduct accordingly, including amending patient monitoring standard operating procedures, providing for virtual safety assessments and where possible, alternative delivery methods.

In addition, the SAHPRA provided for expedited review of COVID-19-related clinical trial applications, with a review timeline of seven to ten working days.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

South Africa had regulatory pathways applicable for emergency approvals of pharmaceuticals or medical devices prior to the COVID-19 pandemic. The SAHPRA had provisions for expedited review of applications for registration of medicines and medical devices in cases of a public health emergency, such as epidemics or pandemics. Under these provisions, the SAHPRA can waive certain requirements for the registration of medicines and medical devices and fast-track the review process to ensure availability of essential medical products in emergency situations. The expedited review is applicable for products already approved by certain international regulatory authorities, or in cases of new products for which there is a strong scientific rationale and evidence of safety and efficacy.

In response to a public health emergency, the SAHPRA may allow for an expedited regulatory process to enable faster approvals for medicines that are not yet available for use in South Africa. The expedited process allows for the accelerated evaluation of applications for registration or emergency use authorisations of diagnostics, therapeutics and vaccines.

Applicants must submit a complete dossier for evaluation, and the SAHPRA will prioritise the evaluation of these dossiers. The authority may also waive certain requirements, such as the need for local clinical data, depending on the product's nature and urgency. However, safety, quality and efficacy requirements are still maintained, and products authorised through this pathway must meet these requirements before being allowed on the market.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

SAHPRA introduced certain flexibilities relating to manufacturing certifications for pharmaceutical and medical device manufacturers during the pandemic to ensure that production of essential products could continue. SAHPRA provided for the extension of validity period of GxP certificates, and introduced remote GxP inspections of manufacturing facilities to reduce the need for in-person inspections during the pandemic.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

South Africa implemented various import/export restrictions and flexibilities in relation to medicines and medical devices due to the COVID-19 pandemic. In March 2020, the South African government issued regulations restricting the export

of certain medical supplies, including personal protective equipment (PPE) and ventilators, to ensure that these supplies remained available in the country during the pandemic.

The South African government also implemented measures to expedite the importation and registration of essential medical products and devices, including COVID-19 diagnostic tests and vaccines. In addition, the SAHPRA introduced several expedited review processes for COVID-19-related products to facilitate quicker regulatory approval of medicines and medical devices. These processes included:

- expedited review of clinical trial applications;
- expedited review of applications for the use of unregistered medical products in the course of an emergency situation;
- COVID-19 emergency use authorisations; and
- fast-track registration of COVID-19 vaccines.

These expedited review processes were put in place to respond to the urgent public health needs created by the COVID-19 pandemic.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Numerous systems were introduced or improved upon to facilitate digital healthcare solutions during and subsequent to the COVID-19 pandemic:

- introductions of mobile health apps, or more features in respect of existing apps;
- developments in telemedicine;
- WhatsApp and SMS-based systems; and
- utilisation of various social media platforms.

These solutions provided access to medical assistance virtually, improved communications, assisted in screening and monitoring of diseases, bettering electronic prescriptions and ensuring compliance with medicines or treatments, or were used simply for educational or awareness campaigns.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

In 2020, South Africa joined with India in petitioning the World Trade Organisation (WTO) to temporarily suspend intellectual property rights in order to ensure accessibility of COVID-19 vaccines and other new technologies for poorer countries. In 2022 the WTO adopted a limited waiver for patents on COVID-19 vaccines, however it is not clear whether this has resulted in additional vaccines being registered or produced in South Africa.

Although the South African Patents Act provides for compulsory licences in certain instances, no such licences have been applied for in respect of COVID-19 vaccines or therapeutics to date. The requirements for the issue of a compulsory licence in South Africa are set out in the Patents Act.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

In order to secure a supply of COVID-19 vaccines, the South African government had to exempt vaccine manufacturers from liability. The mechanism for exempting manufacturers from liability was introduced under the regulations promulgated in terms of the Disaster Management Act, 2002. In an amendment to the regulations published on 22 April 2021, government introduced the COVID-19 Vaccine Injury No-Fault Compensation Scheme. In terms of the published regulations the scheme will only come to an end upon publication of a notice to that effect in the Government Gazette, after the period for submitting claims has expired, and all claims have been finalised.

11.9 Requisition or Conversion of Manufacturing Sites

There were no special provisions relating to the requisition or conversion of manufacturing sites in South Africa in response to the pandemic. However, the South African government did introduce measures aimed at encouraging the local production of pharmaceuticals and other medical supplies during the pandemic. The establishment of a dedicated fund, the COVID-19 Solidarity Fund, assisted with funding for companies to repurpose their existing facilities to manufacture certain essential medical supplies. SAHPRA also produced updated guidelines specifically directed at the licensing of personal protection products such as masks and sanitisers. Some examples of successful efforts to increase local production include the National Ventilator Project (NVP) between the Department of Trade and Industry (DTI) and The Council for Scientific and Industrial Research (CSIR), and an agreement between a local pharmaceutical manufacturer, Aspen Pharmacare, and Johnson & Johnson to manufacture COVID-19 vaccines in South Africa.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

On 15 March 2020, the president of the Republic of South Africa, President Cyril Ramaphosa, declared a national state of disaster in South Africa following the WHO declaring that the COVID-19 outbreak was considered a pandemic. The pronouncement of a state of disaster allowed for emergency procurement of certain named classes of goods (including personal protective equipment, digital thermometers, sanitisers and disinfectants, and body bags) in terms of the Disaster Management Act and an instruction from National Treasury. The national state of disaster as it relates to COVID-19 has since been lifted.